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10/564,635	01/13/2006	Elger Funda	4662-121	2120
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NIXON & VANDERHYE, PC			GREINE, IVAN A	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,635	Applicant(s) FUNDA ET AL.
	Examiner IVAN GREENE	Art Unit 1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 20 July 2010.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-21 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application

6) Other: _____

DETAILED ACTION

Status of the claims

Claims 1-21 are currently pending and are currently being examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14 and 16-21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over SCHNEIDER (US 5,356,636; published October, 1994) in view of BEWERT (EP 0982038; published in German January 2003), KODERA (US 6,455,273; published September, 2002) and ARIA (US 4,921,705; published May 1990); and as evidenced by GERRARD (Trends in Food Science and Technology, 13, 2002, pgs. 391-399) and HAMAGUCHI (US 5,127,953; published July,

1992).

The examiner notes an English translation of BEWERT (EP 0982038), has been ordered and will be forwarded to applicant upon receipt.

Claims 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over SCHNEIDER (US 5,356,636; published October, 1994) in view of BUIKSTRA (US 5,650,190; published July, 1997) and/or NAKAMURA (JP-2002-145771).

The examiner notes an English abstract and a Machine translation of the Japanese language document JP-2002-145771-A1 is attached, and an English translation has been ordered and will be forwarded to applicant upon receipt.

SCHNEIDER teaches stable powderous formulations comprising a fat-soluble active ingredient in a matrix of a (gelatin) protein composition (abstract; claim 1, cols. 1 & 2).

SCHNEIDER does not expressly teach the limitation of a milk protein which is a partially hydrolyzed milk protein with a degree of hydrolysis of 3.5% to 25%. This deficiency in the hydrolyzed milk protein is cured by BUIKSTRA and/or NAKAMURA.

BUIKSTRA teaches heat-stable oil-in-water emulsions stabilized by hydrolysate comprising hydrolyzed protein wherein the protein is a hydrolysate of casein having a degree of hydrolysis of 15% to 70% (title, abstract, 3:12-34).

NAKAMURA teaches powderous compositions comprising fat-soluble vitamin(s) and partially hydrolyzed milk protein wherein the milk protein is casein having a degree of hydrolysis of 5% to 20% (see English Abstract; and Machine translation claims 1-3).

It is the examiners position that the instantly claimed range of partially hydrolyzed milk protein with a degree of hydrolysis of 3.5% to 25% would have been *prima facie* obvious in view of BUIKSTRA and/or NAKAMURA because the degree of hydrolysis range taught by the references overlaps with the

instantly claimed range. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976) (see MPEP §2144.05-I). Furthermore, as per MPEP § 2144.05-II (A), "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)".

Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the hydrolyzed casein protein, as taught by BUIKSTRA and/or NAKAMURA, in the stable powderous formulations of SCHNEIDER because they both teach stable dry powdered food additives containing a fat-soluble vitamin ingredients. The skilled artisan would have been motivated to use casein in the invention of SCHNEIDER because the milk protein would have provided improved nutritional value for mammals¹.

Response to Arguments:

Applicant's arguments filed 07/20/2010 have been fully considered but they are not persuasive.

Applicant's argument's rely on the 37 CFR § 1.132 declaration filed 07/20/2010 in which applicant argues the presented "data that none of the proteins tested were as effective as milk protein in terms of stabilizing features." However, it is noted that applicant does not expressly argue that these results represent "unexpected results" nor do the presented arguments expound on what exactly the "stabilizing feature(s)" are.

¹ See, for example, Brody, Tom; "Nutritional Biochemistry", 2nd ed. 1999, p. 469 § "Protein Quality" first paragraph; Friedman, Mendel; *J. Agric Food Chem.*, Vol. 44, pp. 6-29, particularly p. 8, col. 1, last paragraph; and Hui, Y. H., Editor; Somogyi, Laszlo, P., author; "Handbook of Food Science, Technology, and Engineering," 2006; TAYLOR & FRANCIS; Ch. 83 "Food Additives," p. 83-20, paragraph bridging columns 1 & 2.

Response to Applicant's 37 CFR 1.123 declaration:

Applicant's arguments filed 07/20/2010 have been fully considered but they are not sufficiently persuasive to overcome the rejection based upon obviousness. Firstly, it is noted that the Declarant, Elger Manuel Funda, is an employee of the assignee, and is therefore not considered a neutral party.

The presented data shows a comparison of five formulations (crosslinked and comprising vitamin A acetate) prepared analogously to example 1 of the instant specification. The formulations were prepared and stored at a temperature of 40°C in an open container and the concentration of the vitamin A acetate was measured at the start, and after 2, 4 and 8 weeks. The declaration provides no information about (1) the source or quality of the protein materials used; or (2) how exactly the vitamin A acetate concentration (as shown in the table) was determined. Applicant goes on to provide the opinion evidence that "the milk protein is very similar to gelatin, but significantly and surprisingly better than the other proteins."

It is the examiners position that applicant's results showing an increased stability of casein and gelatin compositions over rape seed (canola) protein, soy protein and rice protein do not represent unexpected results because milk proteins, specifically partially hydrolyzed casein, are taught by the prior art reference ALLEGRETTI² to produce highly stable compositions (see ALLEGRETTI: col. 1, line 49 to col. 2, line 11). Furthermore, the teachings of SCHNEIDER teaches stable powderous formulations comprising a fat-soluble active ingredient in a matrix of a gelatin protein composition. Thus, the prior art suggest what applicant has demonstrated, namely, stable powderous formulations comprising vitamin A acetate in a cross-linked protein matrix. In fact the results show that gelatin and casein are functionally similar, and suggest that substituting the casein taught by BEWERT with the gelatin taught by SCHNEIDER would have been *prima facie* obvious.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6, 8, 12-14, 16, 17 and 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-9, 11, 13-15, 17, 18 and 20-23 of copending Application No. 10/551,197 (hereafter ‘197) in view of BEWERT (EP 0982038;

² Allegretti et al. US 2,897,118 is of record as it was cited by applicant on the IDS dated 18-MAY-2009 (Cite No. A2).

published in German January 2003) and DOXASTAKIS (Novel Macromolecules in Food Systems, pgs 7-38).

Instant claim 1 recites, stable powderous formulations comprising a fat-soluble active ingredient in a matrix of milk protein composition, wherein the protein is thermally cross-linked with a reducing-sugar or a reducing sugar derivative selected from a desoxy sugar or an amino sugar. Instant claims 6 claims the formulation additionally comprises a plant protein; and instant claim 8 claims formulations which further comprise plant protein which is obtained from [...] *lupin protein*. Instant claim 12 recites, formulations wherein the fat-soluble active ingredient is vitamin A, D, E or K, or a carotenoid, or a polyunsaturated fatty acid; Instant claim 13 recites formulations wherein the fat-soluble active ingredient is mixed with a plant or animal fat. Instant claim 14 further limits the reducing sugar to glucose, fructose, saccharose or xylose. Instant claim 17 recites, a process for the preparation of formulations comprising preparing an aqueous emulsion of the fat-soluble active ingredient and the milk protein composition, adding the reducing sugar, converting the emulsion into a dry powder, and submitting the dry powder to cross-linking the protein with heat treatment. Instant claim 21 further limits the plant oil to sunflower oil, palm oil, or corn oil. And instant claim 16 claims a food, beverage, animal feeds, cosmetics or drugs comprising said formulations.

Copending '197 claim 1 recites, a stable powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition which is a native lupin protein isolate having a protein content of more than 90 wt. %, wherein the protein in the matrix is cross-linked and the fat-soluble active ingredient is selected from the group consisting of vitamin A, D, E or K, a carotenoid, a polyunsaturated fatty acid, esters of any of the foregoing, and mixtures of any of the foregoing. Copending '197 claim 11 recites, a process for the preparation of a formulation comprising preparing an aqueous emulsion of a fat-soluble active ingredient and a native lupin protein composition

which is a native lupin protein isolate having a protein content of more than 90 wt. %, wherein a reducing sugar is added and the composition is submitted cross-linking by heating. Instant claim 7 recites the formulation [...] comprising additionally a plant or animal oil or fat. Copending '197 claim 8 recites formulation [...] comprising additionally a reducing sugar. Copending '197 claim 15 limits the reducing sugar to glucose, fructose or xylose. Copending '197 claim 13 is similar to Copending '197 claim 11 except the limitation "cross-linking by heating" is replaced with "converting the emulsion to a dry powder." Copending '197 claim 18 recites a stable powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition which is a native lupin protein isolate having a protein content of more than 90 wt. %, wherein the protein in the matrix is cross-linked with a reducing sugar. Copending '197 claims 20-22 recite limitations similar to claims 1 (the active ingredients), claim 7 and claim 15, respectively.

The difference between Copending '197 and the instant claimed invention is that copending '197 does not explicitly teach the use of native milk protein for the primary cross-linking protein. The deficiency of using a native milk protein is cured by the teachings of BEWERT.

BEWERT teaches dry powder formulations comprising fat-soluble active ingredients in a cross-linked protein matrix wherein the preferred protein is casein ([0001], [0017], [0022], [0026], [0027]). BEWERT further teaches, preferred cross-linkable proteins are gelatin, casein, soy protein, corn protein and collagen ([0017]). DOXASTAKIS teaches lupins belong to the legume group of plants and are able to grow in marginal soils, enabling the plant to grow in many environments (pg. 7, lines 1-6). DOXASTAKIS further teaches, "Interest in a wider utilization of lupin seeds is mainly due to its similarity to soybeans as a high source of protein and to the fact that it can be grown in more temperate climates and is tolerant of poor soils (pg. 7, lines 18-20). .

It would have been *prima facie* obvious to combine copending '197 with the teachings of BEWERT and produce the instant claimed invention because both copending '197 and BEWERT teach

dry powdered food additives with cross-linked protein and a fat-soluble active ingredient in the protein matrix. It is *prima facie* obvious to combine similar compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, i.e. a stable dry vitamin powder. See MPEP 2144.06. It would have been *prima facie* obvious to combine copending '197 with the teachings of DOXASTAKIS and BEWERT because BEWERT teaches that casein and soy can be used interchangeably with their invention and DOXASTAKIS teaches that lupins are a viable alternative to soybeans. Examiner notes the comprising language of copending '197 invites additional ingredients.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments:

Applicant's arguments filed 07/20/2010 have been fully considered but they are not persuasive.

The examiner acknowledges applicant's wish to hold the foregoing provisional obvious-type double patenting rejection in abeyance until allowable subject matter is indicated. Applicant is advised that the Patent Office does not hold rejections in abeyance, therefore the rejection is maintained. See MPEP 714.02 and 37 CFR 1.111(b).

Applicant is reminded that the merits of a provisional obviousness-type double patenting rejection can be addressed by both the applicant and the examiner without waiting for the first patent to issue. *In re Mott*, 539 F.2d 1291, 190 USPQ 536 (CCPA 1976); *In re Wetterau*, 356 F.2d 556, 148 USPQ 499 (CCPA 1966).

Conclusion

The prior art made of record and not presently relied upon is considered pertinent to applicant's disclosure. The following foreign patent documents are made of record: JP-1990-305898 (an English Abstract is provided, and a full English language translation has been ordered and will be forwarded to

applicant upon receipt). The examiner cites Webster's dictionary definitions for the words "matrix" and "native".

Claims 1-21 are pending and have been presented for examination on the merits. The Specification is objected. Claims 1-21 are rejected under 35 USC § 103(a); and claims are provisionally rejected on the grounds of nonstatutory obvious-type double patenting over copending 10/551,197. No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IVAN GREENE whose telephone number is (571)270-5868. The examiner can normally be reached on Monday through Thursday 7AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bonnie Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IVAN GREENE
Examiner, Art Unit 1619

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647